

EXHIBIT 3

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO PLAINTIFF: Diane Bellew (2:12-cv-22473)	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

RULE 26 EXPERT REPORT OF HOWARD JORDI, PhD

I. Background and Qualifications

I, Dr. Howard Jordi received my undergraduate degree in Chemistry from Northern Illinois University in 1967 and my Ph.D. in biochemistry from the same university in 1974.

From 1973-1977, I served in the United States Army Institute of Dental Research where I characterized various drugs contained in biodegradable copolymers of polylactic and polyglycolic acid. I then worked at Water's Associates from 1977-1980. Water's is a world leader in the sale of a wide range of analytical technologies including liquid chromatography, mass spectrometry, rheometry and microcalorimetry. At Waters, I progressed from a Biological Applications chemist to the laboratory manager for the life science division and finally to the Chemicals Applications Manager for the Chromatography Supplies Division.

I am the founder of Jordi Labs and served as president and CEO from 1980-2008. Jordi Labs was founded to provide high quality analytical services to the polymer and plastics industries. In my role as President and CEO, I developed hundreds of analytical methods and have analyzed all of the major polymer systems (polypropylene, polyethylene, urethanes, styrenics, etc.). In this capacity, I have been analyzing polypropylenes for over 25 years. I have de formulated numerous polypropylene samples including identifying and quantifying their additive packages and have been aiding clients for over 25 years in the identification of the root cause of failure in polypropylene systems. I have served extensively as a consultant on polymer related failures for a wide range of industrial clients and have over 40 years of practical experience in the analytical chemistry of polymers. I have in-depth knowledge of a wide range of analytical techniques including FTIR, NMR, DSC, TGA, HPLC, SEM, GPC, DMS, LCMS, GCMS, nanothermal analysis, H-GCMS and PYMS among others. Jordi Labs currently offers over 20 different analytical techniques. I have developed a range of polymeric chromatography columns for polymer molecular weight determination, some of which are patented.

(Attached as Exhibit "A" to this report is a true and accurate copy of my current curriculum vitae.)

II. List of Abbreviations

List of Abbreviations	
DSC	Differential Scanning Calorimetry
DMS	Desorption Mass Spectroscopy
FTIR	Fourier Transform Infrared Spectroscopy
FTIR-Micro	Fourier Transform Infrared Spectroscopy Microscopy
GCMS	Gas Chromatography Mass Spectroscopy
GPC	Gel Permeation Chromatography
GPC-HT	High Temperature Gel Permeation Chromatography
nanoTA	Nano Thermal Analysis
AFM	Atomic Force Microscopy
SOP	Standard Operating Procedure
H-GCMS	Headspace Gas Chromatography Mass Spectroscopy
HPLC	High Performance Liquid Chromatography
LCMS	Liquid Chromatography Mass Spectroscopy
NMR	Nuclear Magnetic Resonance
OM	Optical Microscopy
PYMS	Pyrolysis Mass Spectroscopy
QTOF-LCMS	Quadrupole Time of Flight Liquid Chromatography Mass Spectroscopy
SEM	Scanning Electron Microscopy
SEM-EDX	Scanning Electron Microscopy - Energy Dispersive X-ray Spectroscopy
TEM	Transmission Electron Microscopy
TGA	Thermogravimetric Analysis
~	Approximately

III. Degradation

Degradation Pathways of Polypropylene

Most polymers undergo degradation when exposed to appropriate conditions. Polymer degradation may refer to change in the polymeric properties such as structural integrity, color, shape or tensile strength, to name a few. The degradation process involves several physical and/or chemical processes which are accompanied by structural changes in the polymer leading to significant deterioration of the quality of the polymer.^{1,2,3} There are several different types of degradation mechanisms:

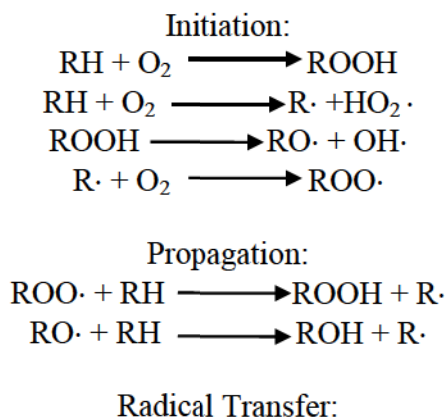
¹ Cornelia Vasile, Degradation and decomposition, in *Handbook of Polyolefin*, eds. Cornelia Vasile and Raymond B. Seymour (Marcel Dekker Inc, New York, USA) 1993, 479-552.

² A. Ravve, Degradation of Polymers, in *Principles of Polymer Chemistry 2nd Ed.*, (Kluwer Academic/Plenum Publishers, New York, USA) 2000. 581-616.

1. Photochemical degradation: Exposure to UV and/or visible light
2. High-energy radiation induced degradation: Exposure to X-rays, γ -rays, etc.
3. Mechanical degradation: Stress forces, abrasive forces during processing or application
4. Thermal degradation: Exposure to heat
5. Chemical degradation: Hydrolysis or exposure to acids, alkalis, salts, reactive gases, etc.
6. Oxidation: Reaction with oxygen, ozone, peroxides, etc.
7. Biodegradation: Interaction with enzymes and microbes
8. Combination of two or more of the above mechanisms

The physiological environment in the human body does not involve many of these conditions such as exposure to light. In the context of non-hydrolyzable hydrophobic polymers (here isotactic polypropylene) used as medical devices oxidation, biodegradation and mechanical degradation pathways are the most pertinent and will be discussed in detail below.

Oxidative degradation: Polypropylene is highly susceptible to attack by oxidants such as atmospheric oxygen, ozone or peroxides.^{4,5,6,7} Oxidative degradation can alter its molecular weight and polydispersity index (PDI) through cleavage of the long polypropylene chains into smaller fragments. The process of oxidative degradation of polypropylene and the steps involved are described in Scheme 1.^{8,9}



³ Devesh Tripathi, *Practical Guide to Polypropylene*, (Rapra Technology Ltd. Shropshire, UK) 2002.

⁴ Cornelia Vasile, Degradation and decomposition, in *Handbook of Polyolefin*, eds. Cornelia Vasile and Raymond B. Seymour (Marcel Dekker Inc, New York, USA) 1993, 479-552

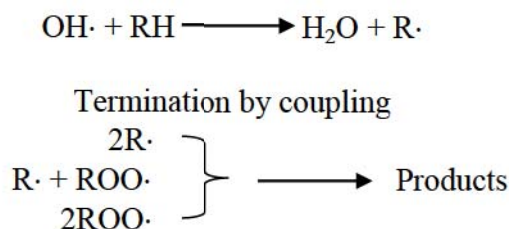
⁵ A. Ravve, Degradation of Polymers, in *Principles of Polymer Chemistry 2nd Ed.*, (Kluwer Academic/Plenum Publishers, New York, USA) 2000, 581-616.

⁶ Denis Bertin, Marie Leblanc, Sylvain R. A. Marque and Didier Siri, *Polymer Degradation and Stability* 95 (2010) 782-791.

⁷ R. A. Silva, P. A. Silva and M. E. Carvalho, *Materials Science Forum* 539-543 (2007) 573-576.

⁸ Cornelia Vasile, Degradation and decomposition, in *Handbook of Polyolefin*, eds. Cornelia Vasile and Raymond B. Seymour (Marcel Dekker Inc, New York, USA) 1993, 479-552.

⁹ Timothy C Liebert, Richard P. Chartoff, Stanley L. Cosgrove and Roberts S. McCuskey *Journal of Biomedical Materials Research* 10 (1976) 939-951.



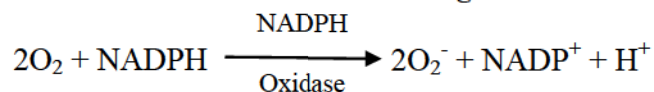
Scheme 1. Mechanism of Oxidative Degradation of Polypropylene (RH = polypropylene)

As a result, polypropylene is an incompatible material under oxidative conditions.^{10,11} While oxidants such as ozone are not present in a biological system, the presence of oxygen (O₂) and its other forms such as superoxides, peroxides and free radicals makes the human body a powerful oxidizing environment to polymers and oxidation occurs via similar processes.¹²

Biodegradation: There is ample evidence in the literature that indicates that polypropylene undergoes degradation in the biological system.^{13,14,15,16} The physiological environment of the polymer can critically control its function and performance.

Upon implantation of polypropylene in the body, white blood cells begin to produce oxidants such as hydrogen peroxide and hypochlorous acid that continue the oxidation induced during sterilization or manufacturing. Oxidation of polypropylene produces more free radicals which causes depolymerization, oxidative degradation, hydrolysis and stress cracking. Enzymes present in the body are able to catalyze these reactions at body temperature. Breakdown of the polymeric chains can then cause the surface of a polymeric implant to crack.¹⁷

Macrophages in the body produce large amounts of both superoxide (O₂⁻) and hydrogen peroxide (H₂O₂) when faced with infectious agents or other foreign materials.¹⁸ This process known as the oxidative burst is the one electron reduction of oxygen (O₂) to O₂⁻ and is catalyzed by NADPH oxidase or NADH oxidase utilizing NADPH or NADH as substrates.



¹⁰ R. A. Silva, P. A. Silva and M. E. Carvalho, *Materials Science Forum* 539-543 (2007) 573-576.

¹¹ Kurt Schwarzenbach, Antioxidants, in *Plastics Additives 2nd Ed.*, R. Gachter and H. Muller (Hanser Publishers, Munich Germany) 1987, 18.

¹² Timothy C Liebert, Richard P. Chartoff, Stanley L. Cosgrove and Roberts S. McCuskey *Journal of Biomedical Materials Research* 10 (1976) 939-951.

¹³ Timothy C Liebert, Richard P. Chartoff, Stanley L. Cosgrove and Roberts S. McCuskey *Journal of Biomedical Materials Research* 10 (1976) 939-951.

¹⁴ Donald R. Ostergard, *International Urogynecology Journal* 22 (2011) 771-774.

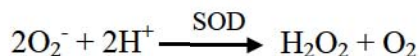
¹⁵ D. F. Williams, *Journal of Materials Science* 17 (1982) 1233-1246 and references therein.

¹⁶ C. D. Klink, K. Junge, M. Binnebösel, H. P. Alizai, J. Otto, U. P. Neumann and U. Klinge, *Journal of Investigative Surgery* 24 (2011) 292-299.

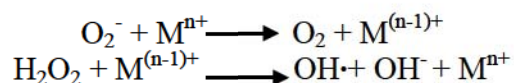
¹⁷ Gina Sternschuss, Donald R. Ostergard and Hiren Patel, *The Journal of Urology* 188 (2012) 27-32.

¹⁸ S. A. M. Ali, S. -P. Zhong, P. J. Doherty and D. F. Williams, *Biomaterials* 14 (1993) 648-656.

Superoxide radicals react to produce hydrogen peroxide with the reaction being catalyzed by superoxide dismutase (SOD).



While both superoxide and hydrogen peroxide can react with polypropylene, the presence of metal ions such as Fe(II) and Cu(I) leads to the generation of hydroxyl radicals which are even more reactive towards polypropylene.



Net Reaction:



The overall net reaction shown above is usually referred to as metal catalyzed Haber-Weiss reaction. Most of the hydroxyl radicals generated *in vivo* are formed from the metal ion dependent breakdown of hydrogen peroxide.

Mechanical degradation: Mechanical degradation or stress-induced cracking of polymers is a degradation pathway which involves irreversible breakdown (cracking, fracture, deformation etc.) of the polymeric material under mechanical stress.^{19,20} Environmental stress cracking (ESC) is cracking of a polymer due to the combined action of a stress and a fluid. It is associated with the phenomenon of crazing and solvent plasticization of the polymer.²¹ As mentioned earlier, the environment of a polymer can have a significant effect on the polymer. The polymer can absorb the fluid surrounding it and the polymer swells causing compressive stress at the surface. This initiates a phenomenon known as crazing which is the mechanical separation of the entangled chains of the polymer. Solvent induced crazes grow more quickly and to greater dimensions than those in inert environments. The crazes that are under the influence of stress act as initiation sites for cracks. Other factors influencing cracking in crazed polymers include time, temperature, molecular weight of the polymer, its structure and thermal history. The stressed chains become mechanically excited. Deexcitation of these chains occurs via various phenomena such as conformational changes, or bond scission/breakage causing the polymer to crack. The ultimate response is a fractured polymeric material. In the conclusion of a 2010 study where polypropylene explants from the human body were characterized, Clave et al. state that "The diffusion of organic molecules into the polymer (especially esterified fatty acids or cholesterol) may be a cause of the

¹⁹ Cornelia Vasile, Degradation and decomposition, in *Handbook of Polyolefin*, eds. Cornelia Vasile and Raymond B. Seymour (Marcel Dekker Inc, New York, USA) 1993, 479-552.

²⁰ Tibor Kelen, *Mechanical Deformation*, in *Polymer Degradation*, (Van Nostrand Reinhold Company, New York, USA) 1983, 157-172.

²¹ R. Chatten, D. Vesely, "Environmental stress cracking of polypropylene" in *Polypropylene An A-Z Reference Polymer Science and Technology Series 2* Ed. J. Karger-Kocsis (1999) 206-214. (ISBN: 978-94-010-5899-5)